by multiple parameters in monitoring and intervention, i.e., [through] a rules engine that use[s] more than one piece of data important to patient care stored in a database. The structure pertaining to the rules engine is set forth for example in Fig. 19 and the Specification where the rules engine (642) searches for patterns [of] data indicative of clinical deterioration on page 39-40. The examiner notes for the record that it has been argued that an intensive care unit can comprise one room on a floor. (Notice of Allowability, page 2.)

A request for reexamination of the '656 Patent was granted on April 7, 2005. Applicant filed amended claims resulting in the issuance of a Reexamination Certificate on September 26, 2006 granting amended claims 1-26. The amended claims were granted over a large number of references, including U.S. Patent No. 6,322,502 issued to Schoenberg et al. (hereinafter, "Schoenberg '502"). The Schoenberg '502 patent is the grandparent of U.S. Application 2005/0125256 (hereinafter, "Schoenberg '256"), which application has been cited in this office action as the basis for rejecting the claims of the present application. Schoenberg '256 was amended to include the claims of the '656 Patent (as issued) in order to provoke an interference with the '656 patent. These claims were added on November 12, 2004, well after the filing of the '656 Patent and well after the filing date of the present application. Schoenberg '256 has yet to be examined.

A second request for ex parte reexamination of the '656 Patent was filed on November 20, 2006, subsequent to the conclusion of the first, earlier ex parte reexamination proceeding (Control No. 90/007,377) of the same patent. A second reexamination order was issued on January 12, 2007. The order cited Schoenberg et al. (WO 98/29790) (hereinafter, "Schoenberg 790"), David et al. (U.S.P. 5,544,649) (hereinafter, "David"), and Kohane, et al. ("Hypothesis-Driven Data Abstraction and Trend Templates," Proceedings of Seventeenth Annual AMIA Annual Symposium on Computer Applications in Medical Care, October 30-November 3, 1993) (hereinafter, "Kohane") as supporting a determination that substantial new questions of patentability had been raised. The order further asserted that Schoenberg '502 was not prior art as to the '656 Patent.

On January 19, 2007, Applicant filed a waiver of its right under 37 C.F.R. §1.530(b) to file a statement on the new questions of patentability cited in the order. An office action was mailed on February 6, 2007. Applicant filed responses to the office action issued in the Second

Reexamination Proceeding on February 15, 2007 and on February 16, 2007.

On June 12, 2007, a Notice of Intent to Issue Ex Parte Reexamination Certificate (NIRC) was issued. The NIRC asserts the following reasons for allowance:

> Independent claims 1 and 17 have been amended to overcome the prior art rejections set forth in this reexamination proceeding. Specifically, these claims have been amended to recite that monitoring and intervention for patients in the plurality of geographically dispersed ICUs "occurs in an automated fashion" at the remote command center 24 hours per day, 7 days per week. This limitation is not taught by the cited prior art patents and printed publications. Claims 2-16 are patentable because of their dependency from claim 1. Claims 18-26 are patentable because of their dependency from claim 17. (NIRC at p. 2.)

The following additional applications claim priority to the '656 Patent and are currently pending:

10/946,548 filed on 09-21-2004
11/061,715 filed on 02-18-2005
11/072,359 filed on 03-04-2005
11/096,189 filed on 03-31-2005
11/118,950 filed on 04-29-2005
11/200,554 filed on 08-10-2005
11/235,512 filed on 09-26-2005
11/236,103 filed on 09-26-2005
11/268,706 filed on 11-07-2005
11/268,748 filed on 11-07-2005
11/444,080 filed on 05-31-2006
11/444,081 filed on 05-31-2006
11/444,082 filed on 05-31-2006
11/444,396 filed on 05-31-2006

C. Claim Rejections Under 35 U.S.C. §103(a)

Claims 9-39 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,772,585 issued to Lavin (hereinafter, "Lavin") in view of Schoenberg '256.

Applicant respectfully traverses the rejections for the reasons presented below.

(1) Schoenberg '256 Is Not Prior Art as to the Present Application

The claims of Schoenberg '256 cited in the office action as the basis for rejecting the claims of the present application are not prior art as to the present application.

Schoenberg '256 claims to be a continuation application of application 09/946,274, filed on September 5, 2001, which claims to be a division of application no. 09/341,065 filed on June 29, 1999 from which Schoenberg '502 issued. The 102(e) date of Schoenberg '502 is June 29, 1999. Thus, the 102(e) date of the Schoenberg '256 disclosure is also June 29, 1999. The present application claims priority as a continuation-in-part of U.S. Application Serial No. 09/443,072 filed November 18, 1999 (from which the '656 Patent issued), which claimed the benefit of U.S. Provisional Application No. 60/141,520, filed June 23, 1999.

Schoenberg '256 was amended to include the claims of the '656 Patent (as issued) in order to provoke an interference with the '656 patent. These claims were added on November 12, 2004, well after the filing of the '656 Patent and well after the filing date of the present application. As discussed in detail below, the original disclosure of Schoenberg '256 does not support the added claims. In the 2nd Reexamination Proceeding of the '656 Patent, it was determined that "the prior art lacks automated analysis on a 24/7 basis (apart from user input)." The prior art referred to in this statement includes WO 98/29790 filed by Schoenberg. The disclosure of Schoenberg WO 98/29790 and Schoenberg '256 are substantively equivalent.

Thus, the added claims are new matter, and the priority date of the added claims is their filing date. The added Schoenberg claims are not, therefore, prior art as to the claims of the present application.

Applicant respectfully submits that based on the foregoing, the added claims of Schoenberg '256 are not prior art as to the present application and requests that the current rejections be withdrawn.

(2)   The Claims of Schoenberg '256 When Read Against the Schoenberg '256 Specification Do Not Teach the Limitations of the Claims of the Present Application

In rejecting claim 9 of the present application, the office action referred to claim 54 of Schoenberg '256.

Schoenberg '256 describes a medical information system that receives patient data and information from various sources and allows that information to be accessed and displayed by medical practitioners in various locations. At its core, it is a distributed display system. It does not teach or disclose the limitations of its newly added claims.

Claim 54 of Schoenberg '256 recites the following limitations (the limitations are labeled for ease of discussion):

54. A method for providing expert critical care simultaneously to a plurality of geographically dispersed intensive care units (ICUs) from a remote location comprising:

[A]   monitoring patient data elements of patients in a plurality of geographically dispersed ICUs;

[B]   communicating over a network the monitored patient data elements to a remote command center, the remote command center comprising a database and a workstation;

[C]   storing the monitored patient data elements in the database, wherein the database comprises stored patient data elements;

[D]   applying a rules engine to at least two patient data elements stored in the database to monitor the medical condition in the patients; and

[E]   utilizing the output from the rules engine to determine if intervention is warranted; and

[F]   wherein the monitoring and determining if intervention is warranted for individual patients occurs 24 hours per day 7 days per week.

Figure 1 of Schoenberg '256 discloses a medical information system 10 comprising a primary display 12, an associated display controller 14, a system storage device 16, a primary interface unit 20, a keyboard and/or pointing device 22, scanner 24, audio input and/or output device 26 and printer 28. All of these elements are coupled by way of interface unit 20 to the display controller 14. As stated in Schoenberg '256, these elements are established by a personal computer (Schoenberg '256 at ¶0030). Bedside unit (BSU)-1, also illustrated in Figure 1 of Schoenberg '256, comprises the elements of the personal computer and separated interface units (designated as I_1, I_2, and I_n).

In addition to BSU-1, Figure 1 of Schoenberg '256 shows BSU-2 interconnected with BSU-1 via a LAN. BSU-1 is also connected to BSU-3 via a modem that connects to the Internet. BSU-1, 2 and 3 each connect to a remote display controller that in turn connects to a remote storage device and a remote display.

Schoenberg '256 defines the problem it intends to solve in terms of "access" to data:

There exists a need for all data and information obtained from and about a patient in a hospital to be immediately and <u>selectively accessible</u> to various members of the medical team in a hospital in accordance with the function performed by those

members. (Schoenberg '256, ¶0009; emphasis added by underlining.)

The data and information in Schoenberg '256 are "selectively" accessible, meaning at the initiation of a user, the data can be seen.

It is noteworthy that Schoenberg '256 does not identify any user or any device as having command over the geographically dispersed ICUs claimed in limitation 54[B]. As illustrated and described, the architecture of medical information system 10 is not hierarchical. Rather, each of the BSUs and each of the remote display and storage systems have the same inherent relationship to the system. That is, the BSUs are peers. In this context, the reference to "a remote command center" as recited in claim 54 of Schoenberg '256 does not teach or reasonably suggest a structure that performs the functions of a remote command center as that term is used in the claims of the present application.

Limitations 54[D] and 54 [E] recite limitations directed to applying a rules engine to at least two patient data elements stored in the database and monitoring the medical condition in the patients and utilizing the output from the rules engine to determine if intervention is warranted. The term "rules engine" is not used in the disclosure of Schoenberg '256. Schoenberg '256 describes a scoring system that relates to the severity of a patient condition. (Schoenberg '256 Specification, ¶0047.) Schoenberg '256 also discloses a medical information calculator "which permits interactive control by a user to perform computations necessary for various medical treatments and/or decisions." (Schoenberg '256 Specification, ¶0066; emphasis added by underlining.)

The scoring aspect of the Schoenberg '256 system and the on-screen medical calculator perform separate functions. Scoring systems have their roots in the observations of Aristotle. Historically, scoring systems were developed to predict the course of a patient's illness and to determine which patients would benefit from therapy and which would not. The burn severity score and the nontraumatic coma index are examples of early scoring systems. Predictive scoring systems, such as the APACHE systems, derive predictive variables for a particular illness through multivarient analysis of large volumes of historical patient data. It is well known in the art that patient scoring can be useful in triaging a patient. (See present application, ¶0075 and ¶155.) Schoenberg '256 uses a formula to determine a score "relating to the severity of a

patient's condition."

Schoenberg '256 describes a calculator that "<u>permits interactive control by a user to perform computations necessary for various medical treatments and/or decisions</u>."   (Schoenberg '256, ¶0066; emphasis added by underlining.) The described medical calculator is responsive to user input.

As noted previously, in the Second Reexamination Proceeding of the '656 Patent, it was determined that "the prior art lacks automated analysis on a 24/7 basis (apart from user input)." The prior art referred to in this statement includes Schoenberg '790. Applicant submits on information and belief that the disclosure of Schoenberg '790 and Schoenberg '256 are substantively equivalent.

While it is not necessary to ascertain the exact meaning of the term "rules engine" as used in claim 54 of the Schoenberg '256 Application, Applicant respectfully submits that a fair reading of the Specification of the Schoenberg '256 Application reveals that unlike the "rules engine" of the present application, the Schoenberg "rules engine" is not automated but requires user input. Thus, claim 54 of the Schoenberg '256 Application does not support a rejection of claim 9 of the present application.

Claims 10-24 of the present application depend directly or indirectly from claim 9. Because claim 9 is not anticipated by the combination of Lavin and Schoenberg, claims 10-24 are also allowable over those references.

The office action cited claim 41 of Schoenberg '256 in rejecting claims 25-39 of the present application. Claim 41of Schoenberg '256 is a system claim that recites limitations that are substantively equivalent to the limitations of claim 54. For the reasons stated in the discussion of claim 54, Applicant respectfully submits that claim 41 is not supported by the specification and drawings of the Schoenberg '256 application. Claim 41 cannot, therefore, be cited to reject claim 25 of the present application. Claims 26-39 of the present application depend directly or indirectly from claim 25. Because claim 25 is not anticipated by the combination of Lavin and Schoenberg, claims 26-39 are also allowable over those references.
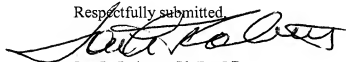
D.   Summary And Conclusions

Based on the foregoing, Applicant respectfully submits that the claims of the present application are allowable over the Schoenberg '256 Application for the following reasons:

- Schoenberg '256 is not prior art as to the present application;

- Even if Schoenberg '256 were prior art, the Schoenberg '256 Application does not teach or reasonably suggest a remote command center as recited in the claims of the present application; and

- Even if Schoenberg '256 were prior art, the Schoenberg '256 Application does not teach or reasonably suggest automated analysis of patient data.

In view of the above information and remarks, Applicant respectfully requests reconsideration of the current rejections.   Applicant submits that based on the foregoing, claims 9-39 are allowable over the cited prior art. Applicant further requests that a timely Notice of Allowance be issued in this case.

Should any further questions arise concerning this application or in the event that the above amendments do not place the application in condition for allowance, Applicant respectfully requests a telephone interview. Attorney for the Applicant may be reached at the number listed below.

Respectfully submitted,

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